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10/511,025	04/28/2005	Jesus Moleiro Mirabal	CLAI-2004002	8755
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EXAMINER				
CUTLIFF, YATE KAI RENE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,025

Applicant(s)

MIRABAL ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 - 41, 44 and 48-58 is/are pending in the application.
- 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41, 44 & 48 - 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 25 – 41, 44, 48 - 58 are pending.
Claims 1 – 24, 42, 43 and 45 - 47 have been canceled
Claims 25 – 34 have been withdrawn.
Claims 35 – 41, 44 and 48 - 58 are rejected.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Response to Amendment

3. The amendment to claims 35, 49 and new claims 55 - 58, submitted August 3, 2009 is acknowledged and entered.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).
5. Correction of the following is required: Claim 48 discloses a peroxide index about between 200 and 1200 units. Examiner notes that this language

Art Unit: 1621

was in claim 9 as originally filed. However, this claimed subject matter is not contained in the specification.

6. Correction of the following is required: Claim 51 discloses a peroxide index about between 200 and 400 units. Examiner notes that this language was in claim 13 as originally filed. However, this claimed subject matter is not contained in the specification.

7. Correction of the following is required: Claim 50 discloses an acid index less than about 15 units. Examiner notes that this language was in claim 11 as originally filed. However, this claimed subject matter is not contained in the specification.

8. Correction of the following is required: Claim 52 discloses an acid index less than about 10 units. Examiner notes that this language was in claim 13 as originally filed. However, this claimed subject matter is not contained in the specification.

9. Correction of the following is required: Claim 57 discloses an emulsion of water and lipid in a 1-50% relation by volume. Examiner notes that this language was in claim 3 as originally filed. However, this claimed subject matter is not contained the specification.

Claim Objections

10. Claims 50 and 52 are objected to because of the following informalities: Claims identify the acid index in units; however, Examples 1 and 2 identify the acid index in mg/g. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 49 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. The MPEP states that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). Further, that the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to

Art Unit: 1621

those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Claim 49 recites the peroxide index of 1100 to 1200 units.

Claim 56 recites that the predominant pathway is partial ozonation...

Examiner can not find support for these limitations in the body of the originally filed Application.

Response to Arguments

14. Applicant's arguments, see pages 6 - 15, filed August 3, 2009, with respect to the rejection(s) of claim(s) 35 – 41, 44 and 48-54 under 35 USC 103(a) have been fully considered and are persuasive, in part, based on the claim cancellations and arguments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Maggiolo, A. (US 2,865,937) and Beal, R.E. (US 3,504,038) in view of Sechi, L.A. et al. (Journal of Applied Microbiology 2001), in view of van Hamersveld et al. (Colloids and Surfaces A, 1999), and further in view of Washuttl et al. (US 5,183,911), Swern et al. (Organic Peroxides, Wiley-Interscience, Vol. I 1970) and Solvents (Wikipedia.en, 2009).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

Art Unit: 1621

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 35 – 41, 44 and 48 - 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Maggiolo, A. (US 2,865,937) and Beal, R.E. (US 3,504,038) in view of Sechi, L.A. et al. (Journal of Applied Microbiology 2001), in view of van Hamersveld et al. (Colloids and Surfaces A, 1999), and further in view of Washuttl et al. (US 5,183,911), Swern et al. (Organic Peroxides, Wiley-Interscience, Vol. I 1970) and Solvents (Wikipedia.en, 2009).

Art Unit: 1621

19. The rejected claims cover, inter alia, a method for obtaining partially ozonized lipids comprising: obtaining an emulsion comprising water and a lipid in a 1-50% relation by volume; passing a gas comprising ozone through said emulsion at a temperature about between 30-50°C, and having a gas flow per-hour rate to lipid volume ratio about between 100 and 500; and employing a quality control parameter including at least one of: peroxide index, acid index, aldehyde concentration, and viscosity. The dependent claims identify the lipid, the gas, the reaction apparatus, the quality control parameters, preferred reaction temperature, and identifies the composition of reaction lipid product as primarily alpha-hydroxi-hydroperoxides.

20. Maggiolo discloses as the first step in her process, the ozonolysis of unsaturated fatty acids in the presence of water at controlled lower temperatures of 0 to 49°C to produce ozonide, (which will includes hydroperoxide). (see col. 1, lines 20-25 & lines 69-70). The ozonization step is performed by passing an ozone-oxygen or ozone-air mixture into the fatty acid at low temperatures with added water. (see col. 2, lines 51-54). Further, Maggiolo teaches that the water and fatty acid in the reaction can be in an equal amount (1:1). (see col. 2, lines 69-70). Also, Maggiolo uses an iodine test solution to determine when the ozonization reaction is complete. (see col. 4, lines 2-8).

21. The difference between Applicant's claimed invention and Maggiolo is as follows: referencing partial ozonization of the lipids; the oil and water being in an emulsion; the water to lipid ratio being in non-equal amounts (i.e. 1:2); the use of the claimed quality control parameters; the various ranges of quality control

Art Unit: 1621

parameters for peroxide index and acid index; the bubbling reactor; that the ozonide produced as primarily alpha-hydroxi-hydroperoxides; the reaction temperature of 50°C; and the claimed gas flow per-hour rate to lipid volume ratio.

22. However, with regard to the partial ozonization of the lipids, the oil and water being in an emulsion, and the water to lipid ratio being 1 to 50%; the Examiner turns to the teaching of Beal. In the process of Beal the first step is the ozonization of the lipids which uses an oil and water emulsion. (see col. 1, lines 13-15 & col. 2, lines 29-35). In Example 1 of Beal it is disclosed that the oil to water ratio is 1 to 2.7 parts by weight of water per part of oil. Further, Beal recognized that a partial ozonization could occur when water and oil emulsion were treated with ozone. (see col. 3, lines 6 – 17). Also, based on Beal's ability to determine the amount of unreacted ozone, it is evident that some form of measuring was being conducted in the Beal process. (see col. 2, lines 61-66).

23. The difference between Applicant's claimed process and Beal is that the reference, like Maggiolo does not disclose which quality control parameters is being used.

24. However, with regard to the use of quality control parameters in the ozonization process, Sechi et al. discloses a process for the ozonization of sunflower oil where the standardization of the preparation was carried out according to parameters that included peroxide index indicators in the ranges of 500 and 800 mmol kg⁻¹; acidity index where the value ranged between 6 and 8 units but it is taught that the level can be less than 25 units; aldehyde concentration; and viscosity. (see page 280, Materials and Methods).

Art Unit: 1621

25. The ozonization process of Applicant's claimed invention are disclosed in the combination of references, Maggiolo and Beal, with the specific form of quality control techniques being taught by Sechi et al. The only differences between the claimed invention and the references are the combination and order of the "old refining steps for producing ozonized lipid". Specifically, the teaching of Maggiolo appears to disclose that the water along with the ozone is added to the unsaturated fatty acid (lipid); wherein the instant claims the ozone is passed through an emulsion of water and lipid. However, Beal passes ozone through an oil and water emulsion. Additionally, neither Maggiolo nor Beal stop their process when they produced the ozonized lipid in their processing sequence. But, there is no requirement in the claims to stop at the ozonized lipid because the claims do not require that the ozonized lipid be isolated only that it is obtained. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teaching of Maggiolo with Beal to produce an ozonides because each of the process have as a major portion of their process the production of ozonide using ozone and lipids. Also, because, according to teaching of Van Hamersveld, bubbling oxygen through oil like sunflower oil, at temperatures of 50° produces hydroperoxides. Then, based on Sechi et al. used the quality parameters to standardize the end product.

Therefore, since all elements of Applicant's claimed process were known in the prior art references of Maggiolo, Beal, Sachi et al. and Van Hamersveld; one skilled in the art could have combined the elements as claimed by suggested and known methods with no change in their respective functions, and the

Art Unit: 1621

combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

26. With regard to the various ranges of quality control parameters for peroxide index and acid index, based on the teaching of Sechi et al., these levels would be standardization parameters based on the desires of the skilled artisan. Especially, since Maggolio and Beal disclose the use of various measuring techniques to determine when ozonization is complete. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance the use of quality control parameters for measuring when the ozonolysis reaction product has obtained the desired levels.

27. With regard to the use of a bubbling reactor the Examiner turns to the teaching Wasuttel et al., wherein an ozone and oxygen mixture are bubbled through the oil to produce the peroxide products. (see col. 2, lines 37-50 & col. 1, lines 29-30). Further, van Hamersveld et al. teaches that in the ozonization of sunflower oil that molecular oxygen is bubbled through the oil. (see page 287, col. 1, para. 3). It would be within the purview of one of ordinary skill in the art familiar with ozonization of lipids that the ozone, oxygen or a mixture thereof can be bubbled through the oil using any commonly known apparatus. Thus, this limitation is deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

28. With regard to Applicant's teaching that the ozonide produced as primarily alpha-hydroxi-hydroperoxides, the Examiner turns to the combined teachings of Swern et al. and Wikipedia. Swern et al. discloses that with the ozonization of olefins in protic, ROH and RCO₂H, the ozonization products are α -oxysubstituted hydroperoxides and peroxides such as, α -hydroxyhydroperoxides. (see pages 32 and 33). It was known in the art at the time of Applicant's claimed process that water was a protic solvent. (see Wikipedia page 1).

Thus, it would have been obvious to one of ordinary skill in the art to at the time of Applicant's claimed process, desiring to produce alpha-hydroxihydroperoxides by the ozonization of a lipid to include water, a protic solvent, since Wikipedia teaches that water is a protic solvent and Swern teaches

Art Unit: 1621

that the ozonization of olefins in protic solvents will produce alpha-hydroxyhydroperoxides.

The prior art teachings disclose that ozonization of lipids, seed oil, produces hydroperoxides and when water is used alpha-hydroxyhydroperoxides are produced. The Courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Also, "an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal-and even common-sensical, we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. (DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1366, 1368; 80 USPQ2d 1641, 1649, 1651 (Fed. Cir. 2006)).

29. With regards to the reaction taking place at temperature of 50°C, the Examiner turns to the teaching of van Hamersveld et al. The van Hamersveld et al. reference teaches that from previous studies on hydroperoxide formation in oil and oil emulsions, it was concluded that hydroperoxide formation can best be

Art Unit: 1621

performed with molecular oxygen at 50°C. (see page 288 col. 2, sentences above first para.). As such, Applicant's claimed process of passing the ozone through the water and lipid emulsion at a temperature of 50°C is an obvious modification of the ozonization process, because, as disclosed by van Hamersveld et al., it was known at time of the claimed invention that that temperature will give the best results in the production of hydroperoxide. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

30. With regard to the gas flow per-hour rate of between 100 to 500 (approximately 0.059 C.F.M. to 0.29 C.F.M.), the Examiner again turns to the teachings of Maggiolo, Beal and van Hamersveld et al.. Maggiolo discloses that the ozonolysis flow rate is carried out at 0.050 C.F.M. (cubic feet per minute), approximately 83.45 liters per hour, for three hours. (see col. 4, lines 2-6). Beal introduced an ozone and oxygen mixture at the rate of 2.4 standard cubic feet per minute, which is approximately 4077.62 liters per hour. In van Hamersveld et al. the process bubbles the oxygen through at oil at a rate of 150 cm³ min, which is approximately 254851.62 liters per hour. The flow rates of each of these references differ based upon the ozonolysis conditions, such production parameters that depend upon the size of the operation. Thus, based upon the

Art Unit: 1621

teaching of the references, this limitation is deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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